JUL 5 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 892.2050.

Submitter:	Materialise Dental NV Technologielaan 15 Leuven Belgium
Establishment Reg. Number:	3006638827
Contact:	Carl Van Lierde Management Representative QARA Materialise Dental NV Technologielaan 15 Leuven Belgium Tel. +32 16 39 6620 Fax. +32 16 39 66 22 Email: Carl.VanLierde@materialise.be
Date Prepared:	January 31, 2012
Trade/ Proprietary Name:	**SimPlant Go**
Common/Usual Name:	Materialise Dental's SimPlant Go software is indicated for use as a medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. It is intended for use as a pre-operative software program for simulating /evaluating dental implant placement and surgical treatment options.
Classification Name/ FDA Reviewing Branch:	Radiology branch
Device Classification/ Code:	Class II - 21 CFR §892.2050 LLZ

<table>
<tr><td>Predicate Device Manufacturer:</td><td>SimPlant® 2011; (K110300)</td></tr>
<tr><td>Purpose of the 510(k) notice:</td><td>The reason for this 510k submission is to request clearance for a device that has been referred to herein as SimPlant Go referenced under 21 CFR §892.2050 and considered a Class II device.</td></tr>
<tr><td>Device Description:</td><td>SimPlant Go allows the individual patient's CT image to be assessed in a three-dimensional way, to see the anatomical structures without patient contact or surgical insult. It includes features for dental implant treatment simulation. Additional information about the exact geometry of the tooth surfaces can be visualized together with the CT data and periodontic procedures with dental implants can be simulated.

The output file is intended to be used in conjunction with diagnostic tools and expert clinical judgment.</td></tr>
<tr><td>Indications for Use:</td><td>Materialise Dental's SimPlant Go software is indicated for use as a medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. It is intended for use as a pre-operative software program for simulating /evaluating dental implant placement and surgical treatment options.</td></tr>
<tr><td>Technological Characteristics :</td><td>Materialise Dental NV's SimPlant Go included in this submission has the same technological characteristics as the previously cleared SimPlant® 2011; (K110300).
Both software devices run on the Windows operating system. The main technological difference between SimPlant Go and the predicate device is the fact that the programming language used is C# as opposed to C++.
SimPlant Go and the predicate device SimPlant 2011 are manufactured by Materialise Dental.
Similarities and differences between predicate and subject device in terms of functions:
<table>
<tr><th rowspan="2">Category</th><th rowspan="2">Features</th><th colspan="2">Available (X) or not (0)</th></tr>
<tr><th>Predicate</th><th>Subject</th></tr>
<tr><td>File open tools</td><td>Open and save .Go projects</td><td>X</td><td>X</td></tr>
<tr><td>Visualization tools</td><td>Visualize gray values (or Hounsfield units) and surface representations (i.e. 3d rendering)</td><td>X</td><td>X</td></tr>
</table>
</td></tr>
</table>

Planning Tools	Selection, sizing and manipulating implant representations for planning /simulating their positions and orientations relative to anatomical structures of interest	X	X
Communication tools:	Link to an online shop	X	X
File open tools	(CB)CT images import; Image selector	X	0
Visualization tools	2D gray value images; Panoramic curve; Volume rendering	X	0
Segmentation tools:	SimPlant Go does not have segmentation tools (e.g. thresholding, region growing, dynamic region growing, manual editing, cavity filling, morphological or Boolean operations)	X	0
Measurement tools:	Gray values around implants; Profile line; Image statistics	X	0
Preparation tools	Reorient axial images to occlusal plane; Nerve; Virtual teeth; Optical scan registration; Dual scan registration; Grafts and volumes	X	0
Planning Tools	Abutments; Fixation screws; Simulation of distraction / osteotomy; Occlusion tool	X	0
Evaluation tools:	Virtual occludator; Soft tissue simulation	X	0
Communication tools:	Distribute View; E-mail project; Upload for support; Save or print screenshot; Capture movie; Export DICOM	X	0

Not having all functions in SimPlant GO as in the predicate device does not impact the safety or effectiveness of the device because:

- The project file is prepared in the predicate device
- Sufficient functionality is available in SimPlant GO to simulate/evaluate dental implant placement and surgical treatment options.

Performance	Software Validation in addition to bench top performance testing was conducted to

Data:	ensure the compatibility of all system components and to support the safety and effectiveness of the device. In particular the following V&V activities were performed: Testing: The testing of the software consisted of unit testing, peer code reviewing, integration testing, IR testing, smoke testing, formal testing, acceptance testing, alpha testing, beta testing. The results of the complete testing are on file in the Materialise Dental offices and are contained within the Design History File. The results of the testing were: - BUGS: differences between software and requirements. The project manager, if necessary after consulting with the application engineer or the acquirer of the project, set the priorities for these bugs; the development manager or team leader assigned a developer to fix the bug. - SUGS: suggestions for improvements on the software. Design Review was performed to decide if these suggestions would be implemented. Validation: Several validation activities were performed: - Design validation - Beta validation by use of mockups, prototypes and internal validation - Clinical Beta validation For SimPlant GO an extensive design validation was performed by an external usability company i.e. Macadamian. Interviews and usability tests were performed. As part of the Beta validation additional usability tests were performed with in total 28 external users and 5 internal users. Clinical case planning in SimPlant GO was validated. All validation criteria were met. Compared to the predicate device SimPlant 2011, SimPlant Go yielded an identical output when using identical input data.
Clinical Data:	N/A
Performance Standards:	DICOM NEMA PS 3.1-3.18: Digital imaging and communication in medicine: 2009 ISO14971: Applications of risk management to medical devices: 2007 ISO 13485: Medical devices Quality Management System: 2003 ISO 9001: Quality Management System: 2008

Substantial Equivalence:

Materialise Dental NV's **SimPlant Go** included in this submission uses similar indications and principles of operation as the previously cleared SimPlant® 2011; (K110300).

	Device comparison table	
	Device for premarket notification	K110300
Trade name	**SimPlant® Go**	**SimPlant® 2011**
Common.name	**SimPlant® Basic Software**	**SimPlant® Software**
Classification	Product Code: LLZ 21 CFR. § 892.2050 Classification Panel: Radiology Device Class: II	Product code: LLZ 21 CFR. § 892.2050 Classification Panel: Radiology Device Class: II
Intended Use	Materialise Dental's **SimPlant Go** software is indicated for use as a medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. It is intended for use as a pre-operative software program for simulating /evaluating dental implant placement and surgical treatment options.	Materialise Dental's **SimPlant® software** is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment.
Material	Software – Magnetic media	Software – Magnetic media
Design	Software for use in pre-operative planning. Materialise Dental's **SimPlant Go** software is intended for use as a software interface for the transfer of imaging information from a medical scanner such as a CT (either conventional multislice or cone beam CT) scanner to a computer file usable in conjunction with other diagnostic tools and expert clinical judgment. The software is intended to be used for simulating / evaluating dental implant placement and surgical treatment options, supporting a wide range of scanners.	Software for use in pre-operative planning. **SimPlant® software** provides a means for image segmentation and advanced pre-operative planning. Surgical templates may be fabricated based on the output of the pre-operative planning.

	Function	The **SimPlant® software** component is used to incorporate the images from either an MRI or CT scan of the affected joint into the specialized planning software. The **SimPlant® software** is used by a qualified surgeon to plan, inspect, fine-tune and approve the pre-surgical plan. The software is used pre-operatively. **SimPlant® software** contains a library of dental implants, and additional instruments for the placement of implants.	**SimPlant® software** is used to incorporate the images from either an MRI or CT scan of the affected joint into the specialized planning software. The **SimPlant® software** is used by a qualified surgeon to plan, inspect, fine-tune and approve the pre-surgical plan. The software is used pre-operatively. **SimPlant® software** contains a library of dental implants, and additional instruments for the placement of implants.
	Programming language	C#	C++
	Operating system	Windows	Windows
	Hardware Testing	N/A	N/A
	Software testing	• Unit testing • Integration testing • IR testing • Smoke testing • Formal testing • Acceptance testing • Alpha testing • Beta testing	• Unit testing • Integration testing • IR testing • Smoke testing • Formal testing • Acceptance testing • Alpha testing • Beta testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Carl Van Lierde
Management Representative QARA
Materialise Dental NV
Technologielaan 15
LEUVEN 3001
BELGIUM

JUL 5 2012

Re: K120733
Trade/Device Name: SimPlant® GO
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 25, 2012
Received: June 1, 2012

Dear Mr. Van Lierde:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K120733

Indications for Use

510(k) Number (if known): K120733

Device Name: **SimPlant® GO**

Indications for Use:

Materialise Dental's **SimPlant Go** software is indicated for use as a medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. It is intended for use as a pre-operative software program for simulating /evaluating dental implant placement and surgical treatment options.

Prescription Use __X___ **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **AND/OR** **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 120733